

Appl. No. : 10/776,309  
Filed : February 11, 2004

#### REMARKS

Claims 31, 32, 34-50 and 99-102 remain pending in the present application, Claims 49 and 99 having been amended. The claims set forth above include markings to show the changes made by way of the present amendment, deletions being in ~~strikeout~~ or ~~[[double brackets]]~~ and additions being underlined.

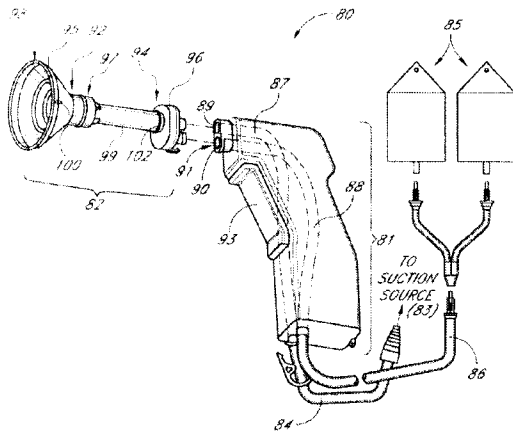
In response to the Office Action mailed March 28, 2007, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

#### Gottesman Does Not Disclose the Irrigation Shield Recited By Claims 99-101

Claims 99-101 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gottesman *et al.* (U.S. Patent No. 4,834,068) (“Gottesman”). Applicant respectfully traverses the present rejections. However, in order to expedite prosecution of the present application, Applicant has amended Claim 99. Applicant expressly reserves the right to further prosecute the original version of Claims 99-102 through continuation practice.

Gottesman discloses a rigid, disk-shaped, shield for use during endoscopic procedures. The shield is disposed between a treating physician and the patient for procedures such as ureteroscopy, colonoscopy, bronchoscopy, and other procedures wherein a telescoping device is introduced to a bodily orifice. The shield is disclosed to have a “frame 40 made from wire, plastic, or any other suitable material.” Gottesman, c. 3, lns. 67-68. This is consistent with the illustrated embodiments shown in Gottesman Figures 1-3, wherein the shield has a frame sufficiently rigid to maintain the shape of the shield without support. Gottesman does not disclose the shield to be a **flexible sheet**. Additionally, Gottesman fails to teach an irrigation shield having an elastically enlargeable aperture configured to releasably engage a head of an irrigation device comprising a flexible splash shield have a **proximal collar and a conical body that diverges in a distal direction away from the collar toward a distal rim**.

In contrast, Claim 99 now recites, among other recitations, “a flexible sheet having an elastically enlargeable aperture configured to fit over and releasably engage a head of an irrigation device comprising a flexible splash shield having a proximal collar and a conical body that diverges in a distal direction away from the collar toward a distal rim.”



**FIG. 13**  
(PRIOR ART)

Applicant would like to point out that Figure 13 of the present Application (reproduced adjacent hereto), which illustrates the prior art, shows an example of the flexible splash shield having a proximal collar and a conical body that diverges in a distal direction away from the collar toward a distal rim recited in Claim 99. As disclosed in the present Specification, the tip 82 includes those features, the collar identified by the reference numeral 97, the distal rim

identified by the reference numeral 98, and the conical body identified by the reference numeral 95.

Thus, when combined with the flexible sheet of Claim 99, the resulting device has two splash shields, the original splash shield formed by the collar 97, conical body 95, and rim 98, as well as the flexible sheet, such as that illustrated in Figure 12 of the present Application.

Gottesman, however, merely discloses a single splash shield. Thus, Gottesman does not disclose or suggest the advantages associated with the irrigation shield recited in Claim 99, e.g., a quick and convenient way to enhance the splash protection provided by a typical aspiration device, such as that shown in Figure 13.

The splash shield illustrated in Figure 13 of the present Application appears to be roughly the same size as that disclosed by the Gottesman reference. Thus, Gottesman utterly fails to teach or suggest any irrigation shield having any similarity at all to that recited in Claim 99, which is configured to fit over and engage a conical splash shield, such as that illustrated in Figure 13 which is approximately the same size as the shield disclosed by Gottesman.

Thus, Applicant submits that Claim 99 clearly and non-obviously defines over the Gottesman reference. Additionally, Applicant submits that Claims 100-102 also define over the Gottesman reference, not only because they depend from Claim 99 but also on their own merit.

Smith et al. Does Not Make Claims 31 and 35-48 Obvious

Claims 31 and 35-48 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,402,724 issued to Smith et al. Applicant respectfully traverses the present rejection.

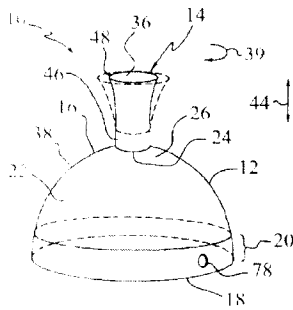


FIG. 1

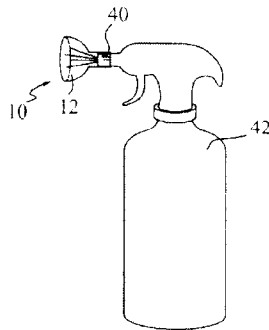


FIG. 2

Smith et al. discloses an irrigation device having a splash shield, as illustrated in Figure 1 and 2. Assuming the pump bottle 42 of Figure 2 of the Smith et al. reference is sized to fit in the human hand, the splash shield 10 is quite small. Additionally, the splash shield 10 includes a collar and a conical body

extending distally away from the collar, like the prior art splash shield illustrated in FIG. 13 of the present Application.

However, Smith et al. does not disclose or suggest an additional flexible sheet that is sized to fit over and engage the conical portion 12 of the splash shield 10. Rather, the shield 10 appears to be something generally similar to the irrigation tip 82 of Figure 13 of the present Application which, as noted above, is admitted prior art. More specifically, as shown in the above reproduction of Figure 13, the tip includes a collar 97, a conical body 95 and a distal rim 98. This appears to correspond precisely to the same structure illustrated in Figures 1 and 2 of the Smith et al. reference, reproduced above.

Thus, Smith et al. fails to teach an additional flexible sheet having an aperture sized to fit over a conical splash shield, such as that illustrated in Figure 12 of the present application.

In contrast, Claim 31 recites, among other recitations, “wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device.”

A non-limiting embodiment of the flexible sheet recited in Claim 31 is illustrated in Figure 12 of the present Application. As disclosed in the present Specification, the flexible sheet of Figure 12 includes an aperture 73 that is sized to fit over the conical body 95 of the tip 82 illustrated in Figure 13. This provides a surgeon or other clinician who is irrigating a wound, a quick and convenient way to enhance the splash protection offered by the relatively small conical

splash shield commonly attached to an operating room irrigation and aspiration device. There is no need to move the patient's body, and there is no need to connect or disconnect couplings to various suction or water supplies, etc. Rather, the flexible sheet can simply be stretched over the conical body 95 and thereby prevent a large watery and contaminated mess in the operating room.

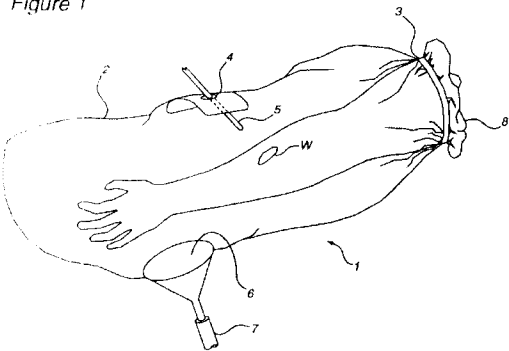
Applicant thus submits that Claim 31 clearly and nonobviously defines over the Smith et al. reference. Additionally, Applicant submits that Claims 35-48 also define over the Smith reference, not only because they depend from Claim 31, but also on their own merit.

Greco Does Not Make Claims 31-32, 34, and 49-50 Obvious

Claims 32-32, 34, and 49-50 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,312,385, issued to Greco. Applicant respectfully traverses the present rejection. However, in order to expedite prosecution of the present application, Applicant has amended Claim 49. Applicant expressly reserves the right to further prosecute the original version of Claims 49 and 50 through continuation practice.

The Greco reference teaches a bag, with or without an internal frame 31, used to prevent irrigation water from splashing on or dripping to the floor of an operating room. The irrigation

Figure 1



device 5 illustrated in Figure 1, reproduced adjacent hereto, appears to include a uniform cross-sectional shape. The specification of the Greco reference identifies this as a “reusable pulse irrigation nozzle 5.” Additionally, the Greco reference discloses that “inlet means 4 can be a self-sealing diaphragm into which pulse irrigation nozzle 5 is inserted.” Greco, col. 4, ll. 62-64. However, Greco fails to teach a

flexible sheet having an aperture that is configured, in an enlarged state, to fit over a conical splash shield of an irrigation device.

In contrast, Claim 31 recites, among other recitations, “wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device.”

Similarly, Claim 49 now recites, among other recitations, “a flexible sheet having an aperture configured to engage an irrigation device comprising a conical splash shield extending distally from a collar attached to the tip of the irrigation device, material of the flexible sheet being configured in size to, in an enlarged state, to fit over the conical splash shield” and “wherein the basin has at least one surface, said surface having at least one convertible portion configured to be convertible between a complete leak-proof wall and an aperture configured to allow the basin to be drained through the aperture.”

As noted above, the Greco reference fails to teach a flexible sheet having an aperture configured to fit over a conical splash shield of an irrigation device.

Thus, Applicant submits that Claims 31 and 49 clearly and nonobviously define over the Greco reference. Additionally, Applicant submits that Claims 32, 34, and 50 also define over the Greco reference, not only because they depend from one of Claims 31 or 49, but also on their own merit.

Additionally, Applicant would like to note, with respect to the convertible portion of the basin recited in Claim 49, that Greco fails to teach a convertible basin.

Applicant recognizes that the Examiner has indicated that the convertible portion being frangible, as recited in Claim 50, “does not patentably distinguish the claimed invention in the prior art,” because it “will yield the same results and therefore, the substitution of one type of convertible portion for another is within the level of ordinary skill in the art.”

However, Applicant would like to note that the Office Action does not address in any way the recitation that the basin has a convertible portion that allows the basin to be converted between a completely leak-proof wall and an aperture configured to allow the basin to be drained through the aperture.

Applicant submits that the present Application includes numerous explanations on the benefits of such a basin. Briefly, however, an advantage that can be provided by such a device is that the basin can be used as a normal irrigation basin for collecting irrigation fluids. However, if a clinician chooses, the clinician can break the frangible portion and use suction available in the operating room to actively drain the basin during use. Thus, the combination of the recited splash shield and a convertible basin provide a novel and non-obvious surgical kit. None of the cited references suggest any such device.

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Thus, Applicant submits that Claim 49 provides yet an additional basis for defining over the Greco reference.

Gottesman et al. Does Not Make Claim 102 Obvious

Claim 102 stands rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,834,068 issued to Gottesman et al. Applicant respectfully traverses the present rejection. However, as noted above, Applicant submits that Claim 99 defines over the cited references. Thus, Applicant submits that Claim 102 also defines over the Gottesman et al. reference, not only because it depends from Claim 99, but also on its own merit.

SUMMARY

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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